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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,981

12/30/2003

Fernand Labrie

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/749,981

Applicant(s)

LABRIE, FERNAND

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/29/07;3/14/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

The response filed April 23, 2007 have been received and entered into the application.

### **Action Summary**

The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Utsumi et al. (U.S. Patent No. 4,005,200) in view of Blum et al. (1983) and Rodriguez (U.S. Patent No. 6,511,970 B1) is being maintained for the reasons stated in the previous Office Action. This rejection is repeated in this Office Action for Applicants' convenience.

Upon further consideration following additional rejection have been made in this Office Action. Therefore, this Office Action is made non-final.

***Claim Rejections - 35 USC § 112***

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is drawn to a method of treating or **reducing the risk of acquiring vaginal dryness** said method comprising increasing levels of a sex steroid precursor selected from the group consisting of dehydroepiandrosterone, dehydroepiandrosterone sulfate, androst-5-ene-3 $\beta$ ,17 $\beta$ -diol and 4-androsten-3,17-dione in a patient in need of said treatment or said reduction, and further comprising administering to said patient a therapeutically effective amount of a selective estrogen receptor modulator as part of a combination therapy. The claim thus encompass a broad population of patient of having risk of acquiring vaginal dryness which must be determined for reduction of such a risk. The instant specification does not describe or exemplify the patient at risk of acquiring such condition, much less any determination factor involving traits or demographic data or cause to identify such patient populations. This instant specification therefore does not provide a basis for one of skill in the art to envision specific populations are at risk of acquiring vaginal dryness. Given the broad population encompassed by the rejected claim, and given the lack of a basis provided by instant specification or prior art to envision the specific population

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who at risk of acquiring vaginal dryness, one of skill in the art would not have been able to envision a broad population having risk of acquiring vaginal dryness to be treated.

Therefore, one of skill in the art would reasonably have concluded Applicants' were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "risk of acquiring" in claim 1 is indefinite because it is unclear how one would determine the risk of acquiring the vaginal dryness without preexisting traits or demographic data to determine the patients at risk of acquiring such condition. One of ordinary skill in the art would not be able to ascertain how to determine those population from having "risk of acquiring" such condition from the population "without" having risk of acquiring the condition. Further, one of ordinary skill in the art would not be able to ascertain the population having the risk of acquiring such condition.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Utsumi et al. (U.S. Patent No. 4,005,200) in view of Blum et al. (1983) and Rodriguez (U.S. Patent No. 6,511,970 B1), both of record.

Utsumi et al. teach dehydroepiandrosterone (DHEA) has been proposed to use clinically in combination with estrogen in the treatment of various syndromes associated with climacterium. (column 1, lines 65-68).

Utsumi et al. do not teach the treatment of vaginal dryness comprising administering DHEA and further comprising selective estrogen receptor modulator (SERM) as part of a combination therapy.

Blum et al. teach that vaginal dryness is one of symptoms associated with climacterium. (abstract).

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Rodriguez teaches SERM are estrogens. (column 41, lines 9-20). Rodriguez teaches the term "estrogen" and estrogen product" includes any estrogen compounds and estrogen equivalents and estrogen agonists and antagonists. (column 18, lines 14-30).

It would have been obvious to one of ordinary skill in the art to employ DHEA in combination with SERM for the treatment of vaginal dryness because Utsumi et al. teach that the combination of DHEA and estrogen is known to have clinical use for the treatment of various syndromes associated with climacterium and that vaginal dryness is one of symptoms or syndromes associated with climacterium. One would have been motivated to employ DHEA in combination with estrogen known by Utsumi et al. for having clinical applicability in treatment of vaginal dryness one of syndromes of climacterium. With regard to combination therapy with SERM is obvious because Utsumi et al. teach that combination treatment of DHEA and estrogen in climacterium syndrome is well known and because SERM are estrogens in general as taught by Rodriguez.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

### **Response to Arguments**

Applicant's arguments filed April 23, 2007 have been fully considered but they are not persuasive. Applicant argues that Utsumi does not disclose the combination of estrogen and DHEA for treating vaginal dryness and Utsumi mentions "various" syndromes associated with climacterium, implying that Utsumi's combination might be useful in some but not all such syndromes without specifying which. This is not found persuasive because Utsumi clearly teach that dehydroepiandrosterone (DHEA) has been proposed to use clinically in combination with estrogen in the treatment of various syndromes associated with climacterium. This teaching encompasses various syndromes associated with climacterium is treatable with the combination comprising DHEA and estrogen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the combination of DHEA and estrogen for the treatment of various syndrome associated with climacterium including vaginal dryness because vaginal dryness is a symptoms associated with climacterium and because the combination comprising DHEA and estrogen including SERM (selective estrogen receptor modulator) is suggested to treat various symptoms associated with climacterium. Applicant argues that Utsumi falls short of showing effectiveness of the combination of DHEA and estrogen because it uses a DHEA ester that Utsumi merely speculates (without proof) might act through a DHEA-mediated mechanism and that Utsumi states only that "it has been proposed" to use the combination of DHEA ester and estrogen, not that such combination had actually been



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used, or shown to be effective. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, there is a clear suggestion from Utsumi reference to employ the combination DHEA ester and estrogen is effectively for clinical use for various syndromes associated with climacterium. Therefore, there is a reasonable expectation of successfully treating various syndromes associated with climacterium by administering DHEA and estrogen as suggested by Utsumi reference for a clinical use. Applicant argues that the Rodriguez reference fails to suggest substituting SERM for estrogen to arrive at applicant's claimed invention because SERMs, as their names, implies, function as estrogen receptor antagonist in some tissues while providing estrogen or estrogen-like effect in other tissues. This is not found persuasive because Rodriguez clearly teaches that the term "estrogen" includes any estrogen compounds and estrogen equivalents and estrogen agonists and antagonist which include SERM as instantly claimed. Applicant argues that that Rodriguez does not treat vaginal dryness, and does not disclose or suggest that SERMs may be used in place of estrogens for that purpose. This is not persuasive because Rodriguez reference was only cited to show that term "estrogen" includes SERMs. Therefore, the employment of combination of DHEA and estrogen for treating various syndromes associated with climacterium including vaginal dryness as taught by Utsumi et al. would encompasses utilization of SERMs because

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SERMs are well known estrogens in view of Rodriguez. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim  
Patent Examiner  
Art Unit 1617

Jmk  
July 16, 2007